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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,944	02/01/2002	Thomas J. Schall	019934-003210US	8775

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,944	SCHALL ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-62* is/are pending in the application.

4a) Of the above claim(s) *50-52,56-58,61 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-49,53-55 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 47-62 are pending. Claims 50-52, 56-58, and 61-62 are withdrawn from examination for being directed at non-elected invention. Claims 47-49, 53-55 and 59 are currently under examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 47-49, 53-55 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rendered indefinite due to the lack of congruency between the preamble of the claimed invention and the purpose that is realized by practicing the claimed invention. The preamble clearly states that the claimed method is for assessing mutations in CMV; however, the practice of the claimed invention results in a detection of the presence or absence of a mutation in the CMV genome. An assessment of mutations differs from a detection of the presence or absence of mutation. According to Webster dictionary, the word "assess" is defined as "to determine the rate or amount of". A detection of a presence or absence of a mutation in the genome is not the equivalent of nor does it remotely related to a determination of the rate or amount of mutation in the genome. Hence, the claims are indefinite.

All other claims are also rendered indefinite for being in dependent form of an indefinite claim.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 47-49 and 54-55 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the Examiner has misunderstood the nature of the invention. The invention does not involve the use of different ligands, each of which recognizes a different CMV mutation to detect the presence and/or the absence of a mutation. Applicant states that the claimed invention, as clarified in amended claim 47, the claimed invention involves collecting CMV and/or at least one CMV infected cell from a patient infected with CMV using a compound that binds CMV and/or a CMV infected cell. A segment of the CMV genome obtained form the collected CMV or CMV infected cell is then analyzed to detect the presence and/or absence of a mutation in the CMV genome. The analysis to detect the presence and/or absence of mutation can be performed using a variety of nucleic acid sequence analysis techniques. Thus, Applicant submits that the specification does adequately describe the currently claims commensurate with the scope of the currently pending claims. The specification

provides an extensive listing of compounds that could be used to bind CMV or a CMV infected cell. Applicant concludes with the submission that the information provided in the specification is sufficient such that one of ordinary skill in the art could reasonably conclude that the inventors were in possession of the currently claimed invention.

Applicant's submissions have been considered, however, are not found persuasive.

The Examiner did not assert that the claimed invention is directed at the use of different ligands, each of which recognizes a different CMV mutation to detect the presence or absence of a mutation. The rejection is made directly at a lack adequate written description for compounds that would indiscriminately bind to CMV in the absence or presence of mutation in CMV--compounds that would recognize CMV regardless of the mutation in CMV. In the instant, the specification does not disclose of a ligand that binds to CMV. Nor does the specification disclose of a ligand that bind to wild type CMV and mutated CMV. The Examiner acknowledges that the specification teaches of several compounds, which Applicant asserts, bind to CMV. However, Applicant's assertion is not substantiated by any evidence. There is no indication that the disclosed compounds bind to CMV. The disclosure does not contain any evidence that would demonstrate that the disclosed compounds indiscriminately bind to CMV in the absence and presence of mutation in the virus. Furthermore, the number of compounds that Applicant provided in the specification does not commensurate with the genus of compounds that is instantly claimed. Nor does the specification provides any guidance concerning the complete or partial structure, physical and/or chemical

properties, functional characteristics, structure/function correlation, and/or a method of making of compounds that indiscriminately bind to CMV. Ergo, Applicant has not reasonably conveyed to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claims 47-49, 53-55 and 59 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant states that the first concern expressed in the office action is that the specification has not shown how compounds can differentiate between wild type and mutated CMV. Applicant submits that this concern is the same as that raised with respect to the written description rejection and has been fully addressed in Applicant's submission under the written description section.

Applicant's submission has been considered. It is found not persuasive. The rejection is made directly compounds that would bind to CMV in the absence or presence of mutation in CMV--compounds that would recognize CMV indiscriminately, regardless of mutation in CMV. In the instant, the specification does not disclose of a ligand that binds to CMV. Nor does the specification disclose of a ligand that binds to wild type CMV and mutated CMV. The Examiner acknowledges that the specification teaches of several compounds, which Applicant asserts, bind to CMV. However, Applicant's assertion is not substantiated by any evidence. Ergo, Applicant has not

disclosed of a ligand that binds to CMV. There is no indication that the disclosed compounds bind to CMV. The disclosure does not contain any evidence that would demonstrate that the disclosed compounds bind to CMV in the absence or presence of mutation in the virus. Furthermore, should the Office missed any evidence that is provided by Applicant that demonstrates that the disclosed compounds binds to CMV, the number of compounds that Applicant provided in the specification does not commensurate with the genus of compounds that is instantly claimed. Nor does the specification provides any guidance concerning the complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and/or a method of making of compounds that indiscriminately bind to CMV. Ergo, Applicant's instant submission is not found persuasive.

Applicant submits that the second issue raised is that the compounds may bind to pathogens other than CMV. Applicant assert that it is the Office's responsibility to submit burden to establish a reasonable basis to question the enablement provided for the claimed invention, while pointing to MPEP § 2164.04 for support. Applicant continues by stating that the Office has not provided any evidence or rationale to justify its conclusion that the compounds bind CMV or CMV infected cells will bind other pathogens and, as such, has not satisfy its burden of demonstrating lack of enablement with respect to this particular issue. Applicant asserts that even if the compound did bind to a pathogen in addition to CMV, the claimed invention is enabling because the sequence of the CMV genome was known at the time the invention. Thus, one of ordinary skill in the art would readily recognize if the nucleic acid was from a source

other than CMV when analyzing the collected nucleic acid obtained. Ergo, Applicant's instant submission is not found persuasive.

Applicant's submission has been considered. It is found not persuasive. Applicant is reminded that it is Applicant's duty to provide an enabling disclosure. Applicant made the original assertion that the disclosed compounds bind to CMV, not the Office. Assertion must be substantiated by sufficient evidence. In the instant, no such evidence is provided. Applicant's assertion that the disclosed compounds bind to CMV is not substantiated by any evidence. The specification does not contain any working examples, **none** [with emphasis]. The specification does not contain any guidance concerning the affinity of the disclosed compounds or any other compounds to CMV, **none** [with emphasis]. The art does not teach the use of the methiothepin and octoclothepin, serotonin and dopamine receptor antagonists, respectively, as CMV ligand, **none** [with emphasis].

Additionally, regarding Applicant's second submission that should the compounds bind to a pathogen other than CMV, the claimed invention remains to be enabling because the genomic sequence of CMV is known at the time the invention. This is not found persuasive. To the contrary to Applicant's assertion, an undue burden of experimentation would be imposed upon the skilled artisan, recall the nature of the invention. The nature of the invention is to assess mutations in CMV by analyzing **a segment of the CMV genome** [with emphasis]. Applicant's claimed invention is not directed at complete genome-to-genome comparison. Applicant's claimed invention is directed at comparison of segments of CMV genome. Thus, one of ordinary skill in the

art would **NOT** [with emphasis] readily recognize if the nucleic acid was from a source other than CMV when analyzing the collected nucleic acid. Ergo, Applicant's instant submission is not found persuasive.

Applicant submits that the third general issue raised concerns ex vivo methods in which blood is withdrawn from a patient. Applicant submits that the specification need not teach what is well known in the art. Applicant submits that it is well known in the art how much sample is necessary to conduct a given analysis. Those in the art would have recognized that many nucleic acid analyses could be conducted with minute quantities of blood. Thus, in some method, only very small amounts of blood are required. Applicant further submits that the even if a larger quantity of blood are withdrawn, the application describes a system for returning the blood.

Applicant's submission has been considered. It is found not persuasive. Applicant is arguing limitations that are not present in the claims. In the instant, the claims do not limit the amount of blood to be withdrawn. The broadest reasonable interpretation of the claims encompasses a continuous withdrawal of blood. Thus, in this regard, Applicant's submission that only a small sample is required is moot. Moreover, the claims do not state a return of the withdrawn blood to the patient. Thus, this regard, Applicant's submission that the blood be returned to the patient is moot. Ergo, Applicant's instant submission is not found persuasive.

With regard to the extraction of CMV from the collector or implant device, Applicant submits that it is not necessary to do so for a number of nucleic acid analysis methods. Applicant also submits that even if extraction is necessary, extraction could be

achieved by competing the CMV with large excess of compounds or other ligands that binds CMV.

Applicant's submission has been considered. It is found not persuasive. Again, Applicant is arguing limitations that are not present in the claims. Nowhere does the claims recite the presence of a device for analyzing mutation. Step (a) of the claimed invention recited collecting CMV by contacting, wherein the claims further limits contacting to comprise withdrawing blood from the patient into or through a collector". Step (a) is not an open-ended step. Step (a) is clearly constricted to the collection of CMV via a specific contacting procedure. Regarding Applicant's submission concerning a technique of collecting CMV, the claims do not recite an outlet for extraction. The collector that is instantly recited is a closed system. Ergo, Applicant's instant submission is not found persuasive.

Applicant submits that the fourth issue presented is directed at to the application of an implant device. Applicant asserts that as noted earlier, analysis can be conducted with minute quantities of sample, thus, it is expected that the implant would only need to be left in for relative short periods.

Applicant's submission has been considered. It is found not persuasive. Again, Applicant is arguing limitations that are not present in the claims. The claims do not recite an outlet for retrieving the CMV collected nor does the claims recite a retrieving of CMV from the implant. Ergo, Applicant's instant submission is not found persuasive.

Cumulatively, the claimed invention is not enabling one skilled in the art to reasonably practice the claimed invention without a reasonable expectation of success. Without i) any guidance from the specification that would reasonably demonstrate that the disclosed compounds or any other compounds have affinity to CMV indiscriminately, regardless of viral mutation; ii) a working example; and iii) any teaching from the prior art concerning the use of the compounds--including the serotonin or dopamine receptor antagonists to capture CMV, the skilled artisan cannot reasonably practice the claimed invention without an undue burden of experimentation. The practice of the claimed invention is an invitation to the skilled artisan to blindly experiment via trial and error. Such experimentation would necessarily impose an undue burden on the skilled artisan. Ergo, the claimed invention remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date

of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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